K082817 pg 3

Section 5

A 510(k) SUMMARY
PERTAINING TO THE SAFETY AND EFFECTIVENESS
OF PRIMUS PSS5 STEAM STERILIZERS

MAY 21 2009

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Date Prepared: May 4, 2009

Introduction:

The PRIMUS PSS5 Steam Sterilizers (or Autoclaves) are **Class II**, Product Code **FLE** Medical Devices as defined by **CFR§880.6880** and defined for use in Hospital operating suites, central sterile supply and clinical laboratories. The PRIMUS PSS5 Steam Sterilize Series provide efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The models contained within this submission request utilize the same technology, materials and updated software as predicate devices cleared under **K991575** except for larger chamber sizes.

The proposed PRIMUS Steam Sterilizer chambers offered within this submission is equipped with the same options offered under the predicate device, in design and construction except for ASME approved (optional) carbon steel reinforced doors, the vessel size and (optional 304 stainless) vessel jackets configured with 316L internal surface stainless steel chambers; offered in either horizontal or vertical sliding door applications. The PSS5-M unit may be pit-mounted, allowing the optional floor carts to roll directly in to the chamber. All large sized sterilizers have pneumatically powered horizontal operating doors, designed to be efficient, reliable and inherently safe. Pass through (double-door) models are also available.

PSS5 sterilizer units offered under this request for clearance are available in Multi-function or Laboratory/Lo configurations. The Multifunction units also offer vacuum, gravity, liquids and test (VAC) configuration, whereas the Laboratory/Lo units offer vacuum, gravity, and low operating temperature configuration.

PRIMUS Steam Sterilizers models contained within this submission are:

The PRIMUS PSS5 series sterilizers are offered with factory pre-set sterilization cycles described within the Indication for Use Table (See attached Table pg 3).

Safety

The PRIMUS PSS5 Steam Sterilizer Series have been validated against FDA recognized consensus standards for electrical safety:

- **AAMI / ANSI / IEC 60601-1-2**, (Second Edition, 2001), Medical Electrical Equipment – Part 1-2: Collateral Standard – General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

Additionally PRIMUS declares conformance to applicable industry and electrical codes as follows

- **UL 61010A-1, IEC 61010-1** Amendment 2, and the Part 2, Particular Requirements for Autoclaves Using Steam for the Treatment of Medical Materials & for Laboratory Process, IEC 61010-2-041, UL 61010A-2-041.
- CNL indicates the product was evaluated to the Canadian Standard for Laboratory Equipment, CAN/CSA-C22.2 No. 1010 and the Part 2, Particular Requirements for Autoclaves Using Steam for the Treatment of Medical Materials and Laboratory Process, CAN/CSA-C22.2 No. 1010.2-041-96.
- PRIMUS PSS5 Pressure Vessels are designed, manufactured and tested in accordance with American Society of Mechanical Engineers **(ASME), Section VIII, Division 1 Unfired Pressure Vessels.**

Validated software designed into the PRIMUS PSS5 series sterilizer provides for fail-safe controls that give appropriate warnings and signals when required conditions have not bee met or if unit malfunctions. The technology designed into the PRIMUS PSS5 Steam Sterilizer Series provides for fail safe controls that provide end users with appropriate warnings and signals when required conditions have not been met or malfunctions occurs. Safety warnings and signals are challenged and verified on each unit, as a function of routine process control testing, during a 100% Factory Acceptance Test conducted at final inspection. Results are documented and maintained in the DHR.

Effectiveness:

PRIMUS has validated sterilizer performance for each load cycle type to ensure that the exposure time, provided in the directions for use statements, have been proven to assure the safety and effectiveness of the PRIMUS PSS5 series sterilizer. Internal validation protocols are documented and deemed to be comply to the ***ANSI/AAMI ST8:2001, Hospital steam sterilizers – (Sterility);*** a harmonized standard recognized FDA as applicable to the validation of steam sterilizers intended for use in hospitals and other health care facilities and that have a volume greater than 2 cubic feet (ft^3) (56 liter [L]) with no exclusions taken. The recognized standard established the minimum construction requirements and performance requirements for hospital sterilizers, using saturated steam as the sterilizing agent.

Declarations of Conformance made by PRIMUS to recognized standards are based on a verification of product performance data, that was independently validated with I indicators were exposed during validation for each cycle type published within the Indications for Use statement. Data output from the validation report was reviewed and found to meet Sterility Assurance Level (SAL) of 10^{-6} when the sterilizer is used and maintained as directed.

Operator Information

PRIMUS provides information in the User's Manual that is intended to ensure safe and effective use of the sterilizer. Additional information concerning recommended practices for end users in monitoring sterilizer performance can be found in the *ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in the health care facilities* or other applicable standards to assure safe and effective use of the steam sterilization processes for application.

Based on the testing and comparison to the consensus standard, PRIMUS concludes that each of the chamber sizes included under this submission performs as intended and raises no new safety or effectiveness issues when used as directed.

Connie L. Mansfield

Marketing Manager
PRIMUS Sterilizer Company, LLC

Load Type	Cycle #	Cycle Type	Sterilize Temp	Sterilize Time (min)	Dry Time (min)	No. of Pre-vacs	Maximum Loading Guidelines		
							Chamber Size 26"x36"x 48"	Chamber Size 35"x57"x [illegible]	Shelving or Optional Loading Equipment
Unwrapped Nonporous Single Instrument	2	Vacuum	132°C (270°F)	4	1	3	1	N/A	Shelving
							1	1	Loading Eq.
Double wrapped instrument 16 lbs each tray	3	Vacuum	132°C (270°F)	4	30	3	12	N/A	Shelving
							12	42	Loading Eq.
Textile packs maximum. size: 9" x 9" x 6", 11.3 lb/ft^3	4	Vacuum	132°C (270°F)	4	30	3	16	N/A	Shelving
							16	42	Loading Eq.
Textile packs maximum size: 9" x 9" x 6", 11.3 lb/ft^3	6	Gravity	121.1°C (250°F)	30	30	0	12	N/A	Shelving
							12	40	Loading Eq.
Vented borosilicate glass containers, 1,000 ml Erlenmeyer flask 4" dia x 7"	7	Liquids	121.1°C (250°F)	30	15*	0	200	N/A	Shelving
							240	480	Loading Eq.
Bowie-Dick Test	8	Test (VAC)	134°C (273°F)	3-1/2	2	3	1 Test Pack	1 Test Pack	N/A

* Est Total Cycle Time includes all phases of the cycle (e.g., purge).
** Dry time in LIQUIDS cycle is liquid cool time.

WARNING

THE INTENDED USE OF A LIQUID CYCLE IS NOT FOR STERILIZING MATERIALS FOR DIRECT PATIENT CONTACT.

WARNING

PRIMUS RECOMMENDS THE VALIDATED FACTORY PRESET CYCLES. CHANGES TO THE CYCLE PARAMETERS, PER ANSI/AAMI ST79:2006, ARE NOT RECOMMENDED. CONTACT PRIMUS FOR FURTHER INFORMATION.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2009

Primus Sterilizer Company, LLC.
C/o Mr. Mark Job
Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K082817
Trade/Device Name: PRIMUS Steam Sterilizers
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: May 7, 2009
Received: May 8, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

Applicant: PRIMUS Sterilizer Company, LLC

510(k) Number: K082817

Device Name: PRIMUS Steam Sterilizers

Indication for Use:

The PRIMUS PSS5 Steam Sterilizer Series are designed for use in the Hospital operating suites, central sterile supply and clinical laboratories. The PRIMUS PSS5 Steam Sterilizer Series provide efficient steam sterilization of non-porous and porous, heat and moisture stabile materials. The PRIMUS PSS5 Steam Sterilizer Series are available in the following configurations:

PSS5-G.1-M***	(32" x 36" x 48" Multi-Functional Sterilizer)	Single or
PSS5-G.1-L***	(32" x 36" x 48" Laboratory/Lo)	Double Door
PSS5-M-M***	(35" x 57" x 60" Multi-Function Sterilizer)	Single or
PSS5-M-L***	(35" x 57" x 60" Laboratory/Lo)	Double Door

Sterilizers are available both in multi-functional models which feature vacuum, gravity, liquids and test (VAC) cycles and Laboratory/Lo-Temperature Models.

The Laboratory/Low Temperature models feature a *cycle* for pasteurization and inspissation processes of items such as infant formula and other liquids requiring lower temperature sterilization. PRIMUS Sterilizer Company, LLC directions for use cautions this OPTION IS NOT RECOMMENDED FOR REPROCESSING ITEMS FOR DIRECT PATIENT CONTACT.

PRIMUS Sterilizer Company, LLC recommends that a suitable chemical indicator or biological challenge test be used on a periodic basis to test effectiveness of the sterilizer in accordance with health care facilities documented plan for monitoring SAL 10^{-6} performance.

The intended use for the sterilizers models listed above is to provide efficient steam sterilization of non-porous and porous, heat and moisture stabile materials, wrapped and unwrapped surgical instruments, hard goods, and linens. The cycles to be cleared for each of the models listed above are found in the table below:

Load Type	Cycle #	Cycle Type	Sterilize Temp	Sterilize Time (min)	Dry Time (min)	No. of Pre-vacs	Maximum Loading Guidelines		
							Chamber Size 26"x36"x 48"	Chamber Size 35"x57"x 60"	Shelving or Optional Loading Equipment
Unwrapped Nonporous Single Instrument	2	Vacuum	132°C (270°F)	4	1	3	1	N/A	Shelving
							1	1	Loading Eq.
Double wrapped instrument 16 lbs each tray	3	Vacuum	132°C (270°F)	4	30	3	12	N/A	Shelving
							12	42	Loading Eq.
Textile packs maximum. size: 9" x 9" x 6", 11.3 lb/ft^3	4	Vacuum	132°C (270°F)	4	30	3	16	N/A	Shelving
							16	42	Loading Eq.
Textile packs maximum size: 9" x 9" x 6", 11.3 lb/ft^3	6	Gravity	121.1°C (250°F)	30	30	0	12	N/A	Shelving
							12	40	Loading Eq.
Vented borosilicate glass containers, 1,000 ml Erlenmeyer flask 4" dia x 7"	7	Liquids	121.1°C (250°F)	30	15*	0	200	N/A	Shelving
							240	480	Loading Eq.
Bowie-Dick Test	8	Test (VAC)	134°C (273°F)	3-1/2	2	3	1 Test Pack	1 Test Pack	N/A

* Est Total Cycle Time includes all phases of the cycle (e.g., purge).
** Dry time in LIQUIDS cycle is liquid cool time.

WARNING **THE INTENDED USE OF A LIQUID CYCLE IS NOT FOR STERILIZING MATERIALS FOR DIRECT PATIENT CONTACT.**

WARNING **PRIMUS RECOMMENDS THE VALIDATED FACTORY PRESET CYCLES. CHANGES TO THE CYCLE PARAMETERS, PER ANSI/AAMI ST79:2006, ARE NOT RECOMMENDED. CONTACT PRIMUS FOR FURTHER INFORMATION.**

(Please Do Not Write Below This Line – Continue on Another Page if needed)

Prescription Use _____ AND/OR Over-The-Counter Use XXX
(Part 21 CFR 801 Subpart D) (Part 21 CFR 01 Subpart C)

ODE Concurrence:

Shuba A Murphy 4/2

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082817

CDRH, Office of Device Evaluation ODE)

510(k) Number _____